MAY 0 8 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Device Description:
The Wilson-Cook Modified Zilver Biliary Stent is indicated for use in palliation of malignant neoplasms in the biliary tree. This device and its introduction system are supplied sterile and intended for single use only.

Trade Name:	Wilson-Cook Zilver Biliary Stent
Common/Usual Name:	Expandable Metal Biliary Stent
Classification Name/Code:	Catheter, Biliary, GU/78 FGE
Classification:	FDA has classified similar devices as Class II, as per 21 CFR § 876.5010. This device falls within the purview of the Gastroenterology and Urology Device Panel.
Performance Standards:	To the best of our knowledge, performance standards for this device do not exist.
Intended Use:	Used to maintain patency of malignant biliary strictures.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Cook Zilver Biliary Stent	Cook Incorporated	K010242

Substantial Equivalence:
The Wilson-Cook Modified Zilver Biliary Stent is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use.

The modification of the Zilver Biliary Stent includes a change to the introduction system only. The stent itself is identical to the predicate Cook Zilver Biliary Stent (K010242) in configuration and materials of construction, and the intended use for both the predicate and modified device are also the same. However, since the predicate introduction system is utilized for percutaneous biliary stent placement and the modified Wilson-Cook Metal Biliary Stent introduction system is used for endoscopic placement, the introduction system of the modified device is longer (200 cm) than that of the predicate device (80 cm).

These devices also operate in the same manner; the main difference being the method utilized in order to gain access to the placement site. The predicate device is used for percutaneous placement, while the modified Wilson-Cook Biliary Stent is placed endoscopically.

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

DEVICE CHARACTERISTIC	Wilson-Cook Modified Zilver Biliary Stent & Introducer [Subject of Special 510(k)]	Predicate: Cook Zilver Biliary Stent & Introducer (K010242)
Intended Use	Indicated for use in palliation of malignant neoplasms in the biliary tree.	Indicated for use in palliation of malignant neoplasms in the biliary tree.
Sterility	Sterile, Disposable	Sterile, Disposable

Biocompatibility:

Reasonable assurance of biocompatibility for the patient-contacting materials has been established through a history of use in similar patient-contacting medical devices and as applicable biocompatibility test results.

Design Control/Risk Analysis/Design Verification:

Design Control, Risk Analysis, Design Verification activities for the subject of this special 510(k) have been conducted in accordance with all applicable internal procedures. The design control process employed is inclusive of the elements as stipulated by 21 CFR Part 820.30, as applicable to the project. The risk analysis performed identified the risks relative to the performance requirements, as specified by our internal procedure for Risk Analysis. The failure mode, effect of failure, severity, potential cause, rate of occurrence, design control element/production controls to eliminate, the potential to detect and our recommended actions were also documented. During Design Verification, dimensional and functional testing to ensure the performance and design integrity of this product line were conducted. All results obtained during our Design Verification met our predetermined acceptance criteria for this product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2002

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K020788
Trade/Device Name: Wilson-Cook Zilver Biliary Stent
Regulation Number: 21 CFR § 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: April 10, 2002
Received: April 11, 2002

Dear Ms. Posner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally §809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020788

Device Name: Wilson-Cook Zilver Biliary Stent

FDA's Statement of the Indications for Use for device:

The Wilson-Cook Zilver Biliary Stent is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020788